**UNITED STATES DISTRICT COURT**
**FOR THE DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | MDL NO. 1456<br><br>CIVIL ACTION NO. 01-CV-12257-PBS<br><br>Judge Patti B. Saris |
| THIS DOCUMENTS RELATES TO: *State of Montana v. Abbott Labs., Inc., et al.*, D. Mont. Cause No. CV-02-09-H-DWM | |

**INDIVIDUAL MEMORANDUM OF BAYER CORPORATION**
**IN SUPPORT OF ITS MOTION TO DISMISS**

In two settlements executed in January 2001 and on April 17, 2003, the State of Montana settled all of its claims against Bayer Corporation ("Bayer") concerning alleged average wholesale price ("AWP") inflation and misreported best prices. Notwithstanding these settlements, the State – by its Second Amended Complaint ("Complaint") – has added Bayer as a defendant to this case. The State's effort to sweep Bayer into an industry-wide litigation despite the company's binding settlements with the State should be decisively rejected.

As explained in greater detail below, to the extent the Complaint identifies specific Bayer products, it addresses the very same subject matter that the settlements conclusively resolved. To the extent the Complaint attempts to sweep more broadly, its allegations are too vague and speculative to survive the standing and particularity standards set forth in this Court's May 13, 2003 opinion. For these reasons, as well as those stated in the Consolidated Memorandum in Support of Defendants' Motion to Dismiss and the individual memoranda of other defendants, plaintiff's claims against Bayer should be dismissed pursuant to Federal Rules of Civil Procedure 9(b), 12(b)(1), and 12(b)(6).

**BACKGROUND**

The Complaint alleges that each of the defendants falsely reported the AWP of their products and provided unlawful financial inducements to providers in order to increase market share and profits. (Cmplt., ¶¶ 7-8, 173, 177-84). In addition, plaintiff alleges that defendants excluded certain discounts and other inducements offered to some purchasers from the calculation of the best price paid for their drugs. (*Id.*, ¶¶ 11-12, 612). Plaintiff contends that, as a result of each defendant's unlawful scheme, both the State and the general public have overpaid for defendants' drugs and the State has been deprived of the full rebate to which it is entitled under applicable Medicaid laws. (*Id.*, ¶¶ 11-12, 14-17, 20, 174, 322).

Nowhere in the Complaint does plaintiff specifically identify any Bayer drugs for which it or its citizens paid. Plaintiff merely states that "Bayer manufactures several drugs reimbursed by the Montana Medicaid Program and which are purchased by citizens of the State of Montana"

and attaches an appendix identifying those drugs for which plaintiff seeks relief. (*Id.* ¶¶ 52, 314 and Appendix A). Rather than alleging concrete facts about specific Bayer products, plaintiff's claims are based solely on vague references to government reports and citations to settlements that not only do not support plaintiff's claims, but actually preclude them.

**ARGUMENT**

The Complaint must be dismissed as to Bayer for two reasons: (1) plaintiff lacks standing to pursue its AWP claims against Bayer, and (2) it has released Bayer both from its AWP claims and its best price claims.

**1.** "[The] threshold question in every federal case" is "whether the plaintiff has made out a 'case or controversy' between himself and the defendant within the meaning of Article III." *Warth v. Seldin*, 422 U.S. 490, 498 (1975). As this Court previously recognized in the context of this multi-district litigation, plaintiff can only proceed with its AWP claims against Bayer to the extent it paid for Bayer drugs. *See In re Pharm. Indus. AWP Price Litig.*, 263 F. Supp. 2d 172, 193-94 (D. Mass 2003). Not only must plaintiff satisfy Article III, but it must do so with the particularity required by Federal Rule of Civil Procedure 9(b). *Hayduk v. Lanna*, 775 F.2d 441, 443-44 (1st Cir. 1985) (state law fraud claims alleged in Federal court must satisfy Rule 9(b)). To do so under this Court's standard, plaintiff must "clearly and concisely" allege the specific Bayer products for which it has paid and their allegedly fraudulent AWPs. *See In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 194.

The statements that "Bayer manufactures several drugs reimbursed by the Montana Medicaid Program and which are purchased by citizens of the State of Montana" and "has stated fraudulent AWPs for all or almost all of its drugs" do not establish a cause of action against Bayer. (Cmplt., ¶¶ 52, 313). As this Court previously admonished other claimants with similarly vague allegations, plaintiff must meet Rule 9(b)'s requirements by particularizing exactly what drugs were paid for and "exactly what the fraud is[.]" *In re Pharm. Indus. AWP Litig.*, Tr. of Jan 13, 2003 Hearing on Mot. to Dismiss, at 74. Plaintiff fails to identify a single

Bayer product for which it or its citizens paid – a failure which is fatal to its claims. *In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 194 (dismissing association plaintiffs who failed to allege specific members who purchased specific drugs). For this reason alone, plaintiff lacks standing to bring its AWP claims as to Bayer and those claims must be dismissed.

Further, plaintiff fails to identify the allegedly fraudulent AWP for each Bayer product listed in Appendix A. Rather, plaintiff merely cites published AWPs for the years 1997 through 2002. (Cmplt., App. A). Simply restating the published AWP does not meet this Court's standard of "clearly and concisely" stating the "allegedly fraudulent AWP" for each drug. *In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 194. Plaintiff's sole attempt to allege a fraudulent AWP for any Bayer drug consists of a confusing reference to two government reports allegedly concluding that the AWPs of immune globulin and Factor VIII pharmaceuticals are generally overstated.[1] Such vague allegations are insufficient to meet either the heightened pleading standard of Rule 9(b) or this Court's clear directives. Plaintiff's claims regarding any drug for which it has not alleged a fraudulent AWP must therefore be dismissed. *In re Pharm. Indus. AWP Litig.*, 263 F. Supp. 2d at 194 (dismissing plaintiffs' claims involving, *inter alia*, "all 'brand named drugs' [and] named drugs without a specific fraudulent AWP"); *see United States ex rel. Gublo v. NovaCare Inc.*, 62 F. Supp. 2d 347, 354-56 (D. Mass. 1999) (dismissing Medicare fraud claims because plaintiff failed to allege why or how defendant's price representations were fraudulent).

In any event, plaintiff is precluded by its 2001 settlement from asserting its AWP claims against Bayer. Plaintiff's AWP allegations mention only Koate-HP®, Kogenate®, and

[1] One Department of Justice ("DOJ") study to which plaintiff refers allegedly determined the "actual" AWP of "two drugs manufactured by Bayer" (Immune Globulin and Factor VIII; only the generic names are identified) and concluded that Bayer's listed AWP for those drugs was overstated by 24% and 119%, respectively. (Cmplt., ¶ 328). Plaintiff also notes a report of the Office of Inspector General which concludes that the AWP of all immune globulin pharmaceuticals were overstated by an average of 32%. (Cmplt., ¶ 329). In typically cryptic fashion, however, the Complaint states that the DOJ report compared its determination of an accurate AWP for the two drugs involved to that "*reported by Abbott*[.]" (Cmplt., ¶ 328 (emphasis added)). The Complaint does not indicate the relevance of this finding as to Bayer.

Gamimune® by name – the same drugs which are the subject of its 2001 settlement with Bayer. (Cmplt., ¶¶ 315, 321, 324, 329-30; Ex. 1, 2001 State Settlement Agreement (Montana), Part II (C)).[2] Indeed, plaintiff attempts to substantiate its otherwise wholly speculative claims by relying on the very settlement which bars them. (Cmplt., ¶ 324). Not only is plaintiff's invocation of the settlement as evidence of wrongdoing improper, it is wholly unavailing. First, the terms of the settlement agreement specifically provide that the agreement "does not constitute an admission by Bayer or evidence of any liability or wrongful conduct." (Ex. 1, Part II(G)).

Second, and even more fundamentally, the settlement explicitly releases Bayer from "any civil or administrative claim, action, suit or proceeding the State has or may have under any source of law for the Covered Conduct." (*Id.*, Part III(2)). The Covered Conduct is exactly that for which plaintiff now seeks relief – namely, inflating the AWP of Koate-HP®, Kogenate®, and Gamimune® and thereby increasing costs to the State under the Medicaid program. (*See id.*, Part II(C)). Plaintiff conveniently fails to disclose that it is one of the forty-seven states that signed the 2001 settlement. Nevertheless, having signed it, plaintiff is now precluded from alleging any claims addressing the conduct at issue and its AWP claims must therefore be dismissed.

2. Plaintiff's best price allegations are similarly futile. Plaintiff's allegations recite exactly the same claims addressed in the 2003 Settlement Agreement and Release pursuant to which plaintiff released Bayer from liability for the conduct at issue. (*Compare* Cmplt., ¶¶ 621-627 and Ex. 2, 2003 State Settlement and Release (Montana), Sec. II(H)). Again, plaintiff conveniently omits the fact that it signed a settlement with Bayer releasing these very claims. Plaintiff is precluded from obtaining a double recovery by seeking to capitalize on claims the

[2] In light of plaintiff's reference to these settlements in the AMCC, the Court may take judicial notice of their contents in considering a Rule 12(b)(6) motion. *See Watterson v. Page*, 987 F.2d 1, 3 (1st Cir. 1993); *see also Romani v. Shearson Lehman Hutton*, 929 F.2d 875, 879 n. 3 (1st Cir. 1991); *Fudge v. Penthouse Int'l*, 840 F.2d 1012, 1015 (1st Cir. 1988), *cert. denied*, 448 U.S. 821 (1988).

release of which it has already agreed to in exchange for its slice of the settlement pie. (Ex. 2, sec. III(1)((B)-(C)).

As in the 2001 settlement, the terms of the 2003 settlement release Bayer from "any civil or administrative claims for damages or penalties that the state of Montana has or may have relating to the Covered Conduct." (*Id.*, Sec. III(2)). Similarly, the Covered Conduct is exactly that for which plaintiff now seeks relief – namely, failing to disclose the best prices for Cipro® and Adalat®, resulting in underpayment of Medicaid rebates. But the 2003 settlement goes even further, incorporating the filings in the underlying Federal criminal action. (*Id.*, Sec. II(F), p. 4). Thus the 2003 settlement releases Bayer from liability for *any* conduct which was the subject of the Federal investigation *or known to the U.S. Attorney at the time of settlement*. (Ex. 2, Plea Agreement, Sec. 4). Moreover, to the extent plaintiff attempts to allege best price malfeasance as to any of the drugs at issue in the 2001 settlement, its claims are similarly barred. The 2001 settlement, in addition to addressing AWP, settled allegations that Bayer misreported the best price (and thereby underpaid Medicaid rebates) for Koate-HP®, Kogenate®, Konyne-80®, and Gamimune. (Ex. 1, Part II(C)(iv)). Thus plaintiff's best price claims as to any drugs at issue in the 2001 settlement must be dismissed as well.[3]

Contrary to the mandate of this Court, plaintiff has failed to identify any drugs for which it has paid or the allegedly fraudulent AWPs of each such drug. Plaintiff's amended complaint is a jumble of vague and conclusory claims, the vast majority (if not all) of which it is barred from asserting against Bayer. Under the applicable standard of this Court, Plaintiff carries the burden of clearly demonstrating what drugs are involved, what the fraud is, and what claims (if any) survive the settlements by which it is bound. Because plaintiff has failed to allege all of the above, let alone with sufficient particularity, its claims must be dismissed.

[3] To the extent plaintiff's allegations are intended to cover a broader time period than the settlements or to allege inflated AWPs or best price malfeasance as to additional drugs, plaintiff has failed to meet even the minimal pleading requirements of Rule 8, let alone the heightened standard of Rule 9(b). *M&I Heat Transfer Products, Ltd. v. Wilke*, 131 F. Supp. 2d 256, 261 (D. Mass. 2001) (requiring a plaintiff asserting a fraud claim to specify the who, what, when, where, and why of the fraud).

## CONCLUSION

For the foregoing reasons, as well as those stated in the Consolidated Memorandum in Support of Defendants' Motion to Dismiss and the individual memoranda of other defendants, Bayer requests that the claims against it in the Second Amended Complaint be dismissed.

Dated: September 15, 2003

Respectfully submitted,

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Exhibit 1

**State Settlement Agreement**

**Part I: Parties**

This Settlement Agreement (hereinafter the "Agreement") is entered into by and between the STATE OF MONTANA (hereinafter the "STATE") and BAYER Corporation (hereinafter "BAYER") (hereinafter collectively referred to as the "Parties") through their authorized representatives.

**Part II: Preamble**

As a preamble to this Agreement, the Parties agree to the following:

A. BAYER Corporation is a corporation organized under the laws of Indiana. Its headquarters are in Pittsburgh, Pennsylvania. BAYER is a manufacturer of pharmaceutical and biological products. Miles, Inc. and Cutter Laboratories, Inc. (which along with BAYER Corporation, shall be referred to hereafter as "BAYER"), were predecessor organizations that ultimately were merged into the company that became known as BAYER Corporation. At all relevant times, BAYER manufactured, marketed and sold certain drugs and biological products to – among others – (1) healthcare providers, (2) "full-line" drug wholesalers, and (3) specialized drug wholesalers sometimes called "distributors."

B. The STATE contends that BAYER caused to be submitted claims for payment to the STATE's Medicaid Program, established by Title XIX of the Social Security Act.

C. The STATE contends that it has civil claims against BAYER under various state statutes and common law for engaging in the following conduct during the period January 1993 through August 1999 involving the marketing and sale of Koate-HP

Antihemophilic Factor (Human), Kogenate Antihemophilic Factor (Recombinant), Konyne-80 Factor IX Complex (Human), Gamimune N, 5% Immune Globulin Intravenous (Human, 5%), Gamimune N, 10% Immune Globulin Intravenous (Human, 10%), and Thrombate III Antithrombin III (Human) (collectively referred to hereafter as the Qui Tam Drugs):

i) The STATE contends that BAYER, in a manner similar to the practices of certain other manufacturers, knowingly and intentionally engaged in a marketing scheme whereby it set the Average Wholesale Prices ("AWPs") of the Qui Tam Drugs at levels far higher than what the vast majority of its customers actually paid for these products when purchasing either directly from BAYER or through a wholesaler. Because the majority of Medicaid programs use AWP as a benchmark in determining reimbursement rates, the STATE contends that as a result of BAYER's actions, BAYER's customers received reimbursement from state Medicaid programs at levels far higher than their actual costs.

ii) The STATE also contends that BAYER knowingly and intentionally misled certain state Medicaid programs that reimburse on the basis of Wholesale Acquisition Cost ("WAC") by, among other actions, representing to third party reporting services such as First DataBank and Medi-Span that it did not sell the Qui Tam Drugs through wholesalers and by misleading Medicaid officials about the prices it charged to wholesale purchasers in order to avoid reporting accurate

wholesale or distributor price information that would have affected the reimbursement levels of the Qui Tam Drugs in states that use WAC as the reimbursement benchmark. As a result, the STATE contends that BAYER's customers received reimbursement from the state Medicaid programs at levels far higher than their actual costs.

iii) The STATE also contends that BAYER knowingly and intentionally misled certain state Medicaid programs that rely on actual acquisition cost information about the prices at which BAYER sold the Qui Tam Drugs to its customers, including home health agencies. The STATE alleges that BAYER did so by falsely reporting its prices on surveys and by providing invoices to home health companies that did not reflect the actual net cost of the Qui Tam Drugs to customers. As a result, the STATE contends that BAYER's customers received reimbursement from the state Medicaid programs at levels far higher than their actual costs.

iv) The STATE contends that BAYER knowingly and intentionally misreported and underpaid its Medicaid Rebates for the Qui Tam drugs, *i.e.*, the amounts that it owed to the Medicaid program under the federal Medicaid Rebate Program, 42 U.S.C. § 1396r-8. BAYER generally was required on a quarterly basis to rebate to each state Medicaid program the difference between the Average Manufacturer Price and "Best Price," as defined by 42 U.S.C. §§ 1396r-8(k)(1) and 1396r-8(c)(1)(C). The STATE alleges that BAYER misreported and

underpaid its Medicaid rebates to all states by calculating its Best Prices for the Qui Tam Drugs without factoring in the value of discounts, rebates, short-dated goods discounts, unrestricted educational grants, free goods, chargebacks, and other price reductions which were not disclosed to the states or the federal government or the Medicaid programs.

BAYER's conduct and transactions referenced herein Paragraph II(C)(i-iv) are hereinafter referred to as the "Covered Conduct."

D. The STATE contends that it has certain administrative claims against BAYER for administrative and monetary penalties under state and federal law for the Covered Conduct.

E. BAYER denies the STATE's contentions as set forth in Paragraphs II (B – D) and denies that it has any liability relating to these allegations.

F. In order to avoid the delay, uncertainty, inconvenience and expense of protracted litigation of these claims, and as a result of mutual desire to settle their disputes, the Parties reach a full and final settlement as set forth below.

G. This Agreement does not constitute an admission by BAYER or evidence of any liability or wrongful conduct.

H. Concurrent with this Agreement, BAYER is entering into a settlement agreement regarding the Covered Conduct with the United States of America and with the relator (the "Relator") in a lawsuit filed pursuant to the qui tam provisions of the federal False Claims Act, Civil Action No. 95-95-1354 (S.D. Fla., under seal), and BAYER also is entering into a Corporate Integrity Agreement with the Office of

Inspector General of the United States Department of Health and Human Services and into similar settlement agreements with numerous other states.

**Part III: Terms and Conditions**

NOW, THEREFORE, in consideration of the mutual promises, covenants, and obligations set forth below, and for good and valuable consideration as stated herein, the Parties agree as follows:

1. (a) BAYER agrees to pay the United States, the individual states and the Relator the maximum collective sum of fourteen million dollars ($14,000,000) (the "Settlement Amount"). BAYER agrees to make payment of the federal share of the Settlement Amount and the Relator's share of the Settlement Amount pursuant to the terms of BAYER's separate settlement agreement with the United States and the Relator. BAYER agrees to pay the maximum sum of six million, one hundred seventy-two thousand dollars ($6,172,000) of this total (the "Total State Settlement Amount"), representing the state-funded portions of the claims settled for the participating states' Medicaid programs, to the participating states identified on Exhibit "A" to this Agreement. The STATE's share of the Total State Settlement Amount is $6,599.26 (the "Individual State Settlement Amount").

   (b) Within three business days of the Effective Date of the federal settlement agreement, the Effective Date of the Corporate Integrity Agreement or the execution of an escrow agreement with the State of New York, whichever is later, BAYER shall deposit the Total State Settlement Amount in an interest bearing escrow account under the custody and control of the State of New

York Medicaid Fraud Control Unit, which shall act as Escrow Agent and shall retain such funds until their release in accordance with the payment terms set forth in c).

(c) The STATE shall be entitled to disbursement of its Individual State Settlement Amount from the escrow account ten days after receipt by the Escrow Agent of a copy of this Agreement executed by both the STATE and BAYER; provided, however, that the STATE shall not be entitled to disbursement of the Individual State Settlement Amount until the Escrow Agent has received fully executed state settlement agreements from all those states identified on Exhibit "B" (the "Threshold States") . Any escrowed funds not disbursed within 200 days after the Escrow Agent has received the Total State Settlement Amount shall be disbursed to BAYER.

2) Subject to the exceptions in Paragraph III(6) below, in consideration of the obligations of BAYER set forth in this Agreement, conditioned upon BAYER's payment in full of the Individual State Settlement Amount, the STATE (on behalf of itself, its officers, agents, agencies and departments) agrees to release BAYER, its parent corporation(s), subsidiaries and affiliates, predecessors, successors and assigns as well as its current and former directors, officers, employees, agents and shareholders from any civil or administrative monetary claim, action, suit or proceeding the STATE has or may have under any source of law for the Covered Conduct. The payment of this settlement amount fully discharges BAYER from any obligation to pay restitution, damages, and or any fine or penalty to the STATE for the Covered Conduct.

3) In consideration of the obligations of BAYER set forth in this Agreement, conditioned upon BAYER's payment in full of the Individual State Settlement Amount, the STATE agrees to release and refrain from instituting, directing or maintaining any administrative claim or any action seeking exclusion from the Medicaid program against BAYER, its parent corporation(s), subsidiaries and affiliates, predecessors, successors and assigns as well as its current and former directors, officers, employees, agents and shareholders for the Covered Conduct as relates to the STATE's Medicaid program, except as reserved in Paragraph III(6), below, and as reserved in this Paragraph.

4) In the event that any person(s) has(have) filed any qui tam "whistleblower" actions under the laws of the STATE relating to the Covered Conduct, it is the STATE's understanding that: such person(s) shall take such actions as are necessary and appropriate to dismiss said actions against BAYER and secure state court approvals, to the extent necessary, of this Agreement; and, the STATE agrees that it shall negotiate in good faith with the person(s) as to the person's(s') share in connection with the state action. In the event that an agreement cannot be reached, the STATE agrees that it shall submit that issue to the state court having jurisdiction. The STATE shall also join in any necessary motions before the state court to secure approvals of this Agreement.

5) BAYER fully and finally releases the STATE, its agencies, employees, servants, and agents from any claims (including attorneys fees, costs, and expenses of every kind and however denominated) which BAYER has asserted, could have asserted, or may assert in the future against the STATE, its agencies, employees, servants, and agents,

related to the Covered Conduct and the STATE's investigation and prosecution thereof.

6) Notwithstanding any other terms of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including BAYER) are any and all of the following:

(a) Any civil, criminal or administrative claims arising under Title 26, U.S. Code (Internal Revenue Code) or the STATE's Revenue Code;

(b) Any criminal liability;

(c) Except as explicitly stated elsewhere in this Agreement, any administrative liability, including mandatory exclusion from any state health care programs;

(d) Any civil or administrative liability that BAYER has or may have under any state statute, regulation or rule not released in Paragraph III(2) above;

(e) Any claims based upon such obligations as are created by this Agreement;

(f) Any express or implied warranty claims or other claims for defective or deficient products or services, including quality of goods and services, provided by BAYER;

(g) Any claims for personal injury or property damage or for other consequential damages arising from the Covered Conduct;

(h) Any claims based on a failure to deliver items or services due; and,

(i) Any civil or administrative claims against individuals, including current or former directors, officers, employees, agents or shareholders of defendant BAYER, who are criminally convicted in relation to the Covered Conduct.

7) BAYER has entered into a Corporate Integrity Agreement with the Office of the Inspector General of the United States Department of Health and Human Services ("OIG"), the goal of which is to ensure the accurate and complete communication of drug pricing information to specified drug price reporting services and the states. BAYER acknowledges that the OIG may share information provided under the Corporate Integrity Agreement with the STATE and that the Corporate Integrity Agreement does not preclude the STATE from taking any appropriate action against BAYER for future conduct under the STATE's laws.

8) BAYER shall report certain drug and biological product pricing information to the STATE's Medicaid Program as set forth herein for the purpose of furnishing the STATE with true pricing information that accurately reflects the prices at which actual purchasers buy the drug and biological products sold by BAYER. BAYER understands that this information may be relied upon by the STATE in establishing reimbursement rates for drugs and biological products.

   a) Price Reporting: Thirty days after the last day of each calendar quarter, BAYER shall report, in accordance with sub-paragraph (b), the average sale price of each of its drugs and biological products identified by BAYER'S NDC codes that are or shall be reimbursed by the STATE's Medicaid Program, to First DataBank and to the STATE's Medicaid Program, except that the first such report shall be submitted on February 28, 2001, or fifteen days after the Effective Date of this Agreement, whichever is later. If appropriate to reflect changes in the sources from which the STATE's Medicaid program